AMENDMENTS TO THE DRAWINGS

The attached replacement sheets of drawings include changes to Figs.10-15.

REMARKS

Claim 1 is pending in the present application and is rejected. Claim 1 is herein amended. Claims 2 and 3 are herein added. No new matter has been added.

Information Disclosure Statement

The Office Action indicates that the references cited in the Search Report have not been considered, although only the International Search report itself and JP 2-104052 are lined through on the PTO/SB/08 form. The Office Action states that the reference JP 2-104052 was not considered because it is not in English. In response, Applicants respectfully submit that this is improper. As explained in MPEP 609.04(a)(III):

> Where the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report. (emphasis added).

An English version of the International Search Report was submitted, and "Y" was indicated for JP 2-104052 on the search report. This is sufficient to qualify as a concise statement of relevance. As such, Applicants respectfully request that the Office provide a revised initialed PTO/SB/08 form in which JP 2-104052 and the Search Report are initialed as having been considered.

Applicants' Response to Objections to the Drawings

The Office Action objects to the drawings because the following reference numbers are included in the drawings but are not explained in the specification:

Figure 10: 10a
Figure 11: 10a
Figure 12: 13d and 13g
Figure 13: 13d and 13g
Figure 14: 14b and 14d
Figure 15: 14b and 14d

In response, Applicants herein revise Figures 10-15 in order to delete the reference numerals from the drawings.

Also, the Office Action indicates that reference numeral 3k does not point to anything in Figure 11. Applicants herein correct Figure 11 such that this reference numeral is moved to where there is a lead line without a number (the lead line terminating just below "9b"). Favorable reconsideration is respectfully requested.

Applicants' Response to Objections to the Specification

The Office Action objects to the specification for several reasons. First, the Office Action mentions the abstract of the disclosure, but does not object to any specific language. However, since the specification was 152 words, Applicants herein amend it to be less than 150 words and to use language which better conforms to U.S. practice.

Next, the Office Action notes two typographical errors. Applicants herein correct these errors in the response.

Finally, the Office Action refers to trademarks in the specification. Applicants herein amend the specification such that each of "FLUTIDE DISCUS," "PULMICORT TURBUHALER," "DISKHALER" and "ROTADISK" are capitalized as per U.S. practice. Applicants note that the paragraphs referred to in this amendment relate to the paragraph numbering of the publication of the application (US 2007/0272235). Favorable reconsideration is respectfully requested.

Applicants' Response to Claim Rejections under 35 U.S.C. §112

Claim 1 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

The Office Action points to the phrase in claim 1 which recites that the sound is produced when "an inhalation has been performed without fail." However, the Office Action indicates that "there is no way to be sure of this without undue experimentation." Applicants are unclear as to whether it is meant that the skilled artisan would not know how to make an inhaler which produces a sound when inhalation is correctly performed, or whether it is meant that a skilled artisan would not know how to use the inhaler in order to make a sound when inhalation is correctly performed.

In response, Applicants herein amend the claims to recite that the sound is produced when "inhalation has been correctly performed," instead of reciting that the sound is produced when "inhalation has been performed without fail." This language is more consistent with the specification. Additionally, Applicants respectfully note that if this enablement rejection is

maintained, the Examiner should explain the rejection in greater detail, by applying the *Wands* factors in accordance with MPEP 2164.01(a), for example. Favorable reconsideration is respectfully requested.

Claim 1 was rejected under 35 U.S.C. §112, second paragraph, as failing being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is the position of the Office Action that claim 1 is indefinite for two reason. First, the Office Action states that it is unclear if the "inhaler aid" or the "reed" are being positively claimed. In response, Applicants herein amend the claims in order to clarify the intended subject matter. The amended claims make it clearer that the positively recited device is the inhaler aid, and that the reed is a positively recited feature of the inhaler aid.

The Office Action also objects to the claim on the grounds that the terms "the minute powdery curative medicine," "the end" and "the inhaler" do not have proper antecedent basis. In response, Applicants herein amend the claims in order to provide proper antecedent basis. Additionally, Applicants note that antecedent basis for "the inhaler" is found in line 3 of the claim: "...used to aid an inhaler..." Applicants also herein make other minor amendments in order to improve the clarity and form of the claims. Favorable reconsideration is respectfully requested.

Applicants' Response to Claim Rejections under 35 U.S.C. §103

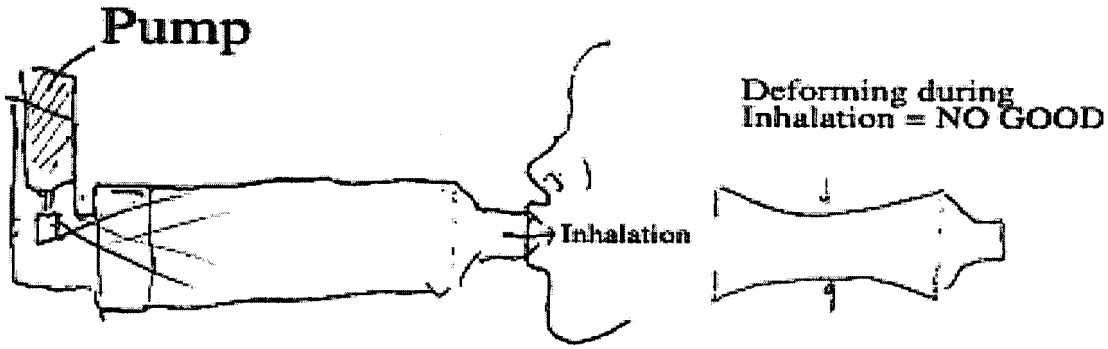
Claim 1 was rejected under 35 U.S.C. §103(a) as being unpatentable over Puderbaugh (U.S. Patent No. 6,026.807) in view of Kinkade (U.S. Patent No. 5,062,422).

It is the position of the Office Action that Puderbaugh discloses the embodiment as claimed, with the exception of teaching (i) that the tube is made of silicon rubber, and (ii) that the sound is produced when the inhalation is correctly performed, and (iii) that the inhaler aid includes a horn-shaped junction and left and right projections including holding members on the ends. The Office Action states that (i) and (ii) would have been obvious, and relies on Kinkade to teach (iii).

Puderbaugh is directed at a metered dose inhaler cloud chamber. In Figure 1, Puderbaugh discloses a configuration where a spacer 100 is positioned between a holder 15 of a container 10 and a mouthpiece 70. The spacer 100 is illustrated in greater detail in Figure 3, and includes a cloud chamber 50, a sleeve 52, and a chamber cap 60. Puderbaugh discloses that a whistle 30 is inserted into the distal end 51 of cloud chamber 50 by inserting a reed 30a into an opening 31. Puderbaugh discloses that "the reed 30a is set to vibrate emitting an audio signal to the patient in the event that the rate of inhalation being applied in breathing the expiratory air exceeds a range suitable for normal inhalation." Column 4, lines 7-10 (emphasis added).

Kinkade is directed at an offset anatomical mouthpiece. As illustrated in Figure 1, the mouthpiece 10 includes a coupling 1. The mouthpiece includes wings 3 with a lip 4 between the wings 3. Kinkade discloses that the mouthpiece can be applied to underwater breathing devices, as well as "inhalators and gastric tubes for medical equipment." See column 1, lines 10-15.

In response, Applicants first respectfully submit that it would not have been obvious to modify Puderbaugh to include a tube of silicon rubber. Puderbaugh is directed at ensuring that a drug is slowly inhaled by dispersing the drug into a "mist" kept in a "mist chamber." In order for this to occur, the cloud chamber 50 must be rigid. This "mist chamber" or "cloud chamber" is a spacer, which must not change shape when the patient inhales the "mist."



Therefore, the cloud chamber of Puderbaugh is a round tube formed of hard plastic. If the cloud chamber 50 were made of silicon rubber, it would be allowed to deform. If deformation occurs, then the device of Puderbaugh would become unable to perform its intended function of producing a sound when inhalation is performed *too quickly*. If the cloud chamber were made out of silicon rubber and the user inhaled too quickly, the result would be that the cloud chamber would deform and the sound would either not be produced, or would be too quiet to hear. As such, Applicants respectfully submit that it would not have been obvious to modify the combination of Puderbaugh and Kinkade in order to provide for a tube made of silicon rubber. Such a modification would have rendered Puderbaugh unsatisfactory for its intended purpose. If a proposed modification would render the prior art invention being modified unsatisfactory for its

intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP 2143.01.

Additionally, Applicants respectfully submit that even if, *arguendo*, the proposed modification of Puderbaugh were made, the claimed apparatus is still structurally distinct from such a modified Puderbaugh device. Applicants respectfully submit that in the claimed embodiments, the reed will make a sound when the inhalation is *correct*. On the other hand, in Puderbaugh, whether modified or unmodified by Kinkade, the reed will not make a sound when the inhalation is correct. Puderbaugh is designed to make a sound when inhalation is *incorrect*, and this function would be removed by the proposed modification. In order for this functional difference to occur, there inherently must be an additional structural difference between Puderbaugh and the claimed embodiment. As such, the combination of cited art does not disclose or suggest the embodiment as claimed.

Furthermore, the proposed combination of cited art is additionally structurally distinct from the claimed apparatus in that it lacks a horn-shaped junction as claimed. The Office Action argues that element 6 of Kinkade discloses this. However, the element of Kinkade referred to by the Office Action is a component of the mouthpiece of the cloud chamber of the proposed modification. However, the claims require that the horn-shaped junction is a part of the inhaler aid which attaches to the mouthpiece of the inhaler. In the proposed combination of the Puderbaugh, the sleeve 52 which attaches to the holder 15 is not a horn-shape. Rather, it is a cylindrical shape. As such, the combination of cited art does not disclose or suggest the embodiment as claimed. Favorable reconsideration is respectfully requested.

Finally, Applicants herein provide the following additional explanatory comments. A person's oral cavity has a small capacity of only about 50cc. The "mist chamber" of the Puderbaugh Cloud Chamber is designed to be bigger than the capacity of a person's oral cavity according to the age of the user. This is because the goal of the "mist chamber" is to hold one dose of injection/aerosol asthma medicine while it is gradually inhaled. Therefore, when a dose of aerosol is injected, some amount exceeds the capacity of the oral cavity and escapes to the atmosphere, *i.e.* is wasted. Even if the injection amount is constant, the amount of medicine that a patient inhales is not constant. At the same time, some amount of the medicine injected into the oral cavity in mist form sticks to oral membranes and does not reach the lungs. It is also noted that the Puderbaugh cloud chamber is an aid created for the old aerosol inhalable medicines. It is impossible for the current generation of trace minute powdery curative inhalable medicines to comply with the same logic as the aerosol of a generation ago. Due to the sizeable defects above, the new asthma therapeutic medicines and influenza medicines made by pharmaceutical companies are all in minute powdery curative medicine form. Currently, the amount of therapeutic minute powdery curative medicine is 0.05mg to 0.1mg.

The "mist chamber" of the Puderbaugh cloud chamber is a "spacer" so that the aerosol does not escape from the oral cavity. In the present invention, the distance between the device 10b and mouthpiece 2 is required to be as small as possible. In the present invention, a "spacer" such as that in Puderbaugh would be useless or even harmful "dead space." The claimed embodiments have as an aim to allow a prolonged intake into the lungs, all at once and at the greatest inhalation speed/inhalation amount possible for the patient of an extremely small amount

of minute powdery curative medicine, generally about .05 to 0.1 mg. Furthermore, the reed makes a noise each time for a correct inhalation (as quickly and deeply as the patient is capable of), and lets the patient know that the inhalation was correct each time.

New Claims

In addition, Applicants herein add new claims 2 and 3. These claims more clearly recite that the inhaler aid is adaptable to be used to a minute powdery medicine. When using this type of medicine, the patient must inhale the medicine as quickly as possible. On the other hand, Puderbaugh is designed for use with aerosolized liquid medicine. This type of medicine should be misted in the cloud chamber 50 and then inhaled slowly. If minute powdery medicine was used with the device of Puderbaugh, even if modified as proposed by the Office Action, it would not work because the aerosolized liquid medicine would get stuck to the sides of the cloud chamber, for example. Favorable consideration is respectfully requested.

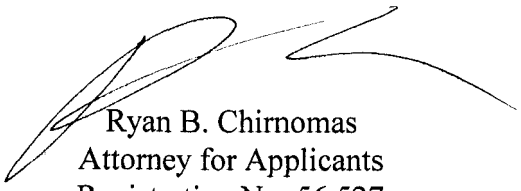
For at least the foregoing reasons, the claimed invention distinguishes over the cited art and defines patentable subject matter. Favorable reconsideration is earnestly solicited.

If the Examiner deems that any further action by applicants would be desirable to place the application in condition for allowance, the Examiner is encouraged to telephone applicants' undersigned attorney.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP



Ryan B. Chirnomas
Attorney for Applicants
Registration No. 56,527
Telephone: (202) 822-1100
Facsimile: (202) 822-1111

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Enclosures: Replacement Drawing Sheets